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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,289	03/23/2001	Carl R. Merrill	PAN01/001	6112

7590

09/30/2002

Mary E. Gormley  
Shaw Pittman LLP  
1255 23rd Street NW  
Washington, DC 20037-1128

EXAMINER

GUCKER, STEPHEN

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 09/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/816,289

Applicant(s)

MERRIL ET AL.

Examiner

Stephen Gucker

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

**DETAILED ACTION**

***Election/Restrictions***

1. All previous Restriction requirement(s) (Paper No. 4 June 4<sup>th</sup>, 2002) are hereby rescinded.
2. The current Restriction requirement is now in effect (Paper No. 6 September 26<sup>th</sup>, 2002).
3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-4 (each in part), drawn to a method for treating a neurodegenerative disease in a mammal, comprising administering to said mammal nicotinamide which will inhibit and/or reverse ADP-ribosylation of elongation factor-e (EF-2) in neuronal cells thereof, whereby neuron degeneration is ameliorated, classified in class 532, subclass 1, for example.
  - II. Claims 1, 3, and 4-8 (each in part), drawn to a method for treating a neurodegenerative disease in a mammal, comprising administering to said mammal a vaccine composition containing diphtheria toxin which will inhibit and/or reverse ADP-ribosylation of elongation factor-e (EF-2) in neuronal cells thereof, whereby neuron degeneration is ameliorated, classified in class 424, subclass 239.1, for example.
  - III. Claims 1, 3, 4, and 9-14 (each in part), drawn to a method for treating a neurodegenerative disease in a mammal, comprising administering to said mammal an antibody which will inhibit and/or reverse ADP-ribosylation of

elongation factor-e (EF-2) in neuronal cells thereof, whereby neuron degeneration is ameliorated, classified in class 424, subclass 130.1, for example.

- IV. Claims 15-19 21-26, drawn to a method of determining if an agent is useful for treating a neurodegenerative disease, classified in class 435, subclass 6, for example.
- V. Claim 20, drawn to an agent effective in preventing inhibition of translation by diphtheria toxin or exotoxin A, classification dependent upon agent structure.

4. The inventions are distinct, each from the other because of the following reasons:

5. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, II, III, and IV are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of administering nicotinamide to a mammal, which is not required by any of the other Inventions. Invention II requires search and consideration of administering a vaccine composition to a mammal, which is not required by any of the other Inventions. Invention III requires search and consideration of administering an antibody to a mammal, which is not required by any of the other Inventions. Invention IV requires search and consideration of determining if an agent is useful for treating a neurodegenerative disease, which is not required by any of the other Inventions.

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6. Inventions IV and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the agent can be prepared by processes which are materially different from the method of Invention IV, such as by chemical synthesis, or by isolation and purification from natural sources.

7. Inventions VI and each of I, II, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VI and each of I, II, and III are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, II, and III do not recite the use or production of the agent of Invention VI.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirements, restriction for examination purposes as indicated is proper.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN  
September 26, 2002

*Gary L. Kunz*  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1000